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Docket No. F-7125

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Stefan BRACHT
Serial No. : 09/937,534
Filed : September 26, 2001
For : TRANSDERMAL THERAPEUTIC SYSTEM WITH
NICOTINE AND ADDITION OF MONOTERPENE
KETONES
Group Art Unit : 1615
Examiner : Micah Paul Young
Confirmation No. : 9613
Customer No. : 000028107

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C. Bruce Hamburg
(Name)


(Signature)

MAIL STOP REPLY BRIEF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

REPLY BRIEF

Sir:

This brief, submitted in triplicate, is in reply to the Examiner's Answer,
mailed June 3, 2004.

Related Appeals and Interferences

It appears that the Examiner has overlooked that the statement in question appears at page 2 of the Appeal Brief.

Rebuttal of Assertions in the Examiner's Answer

The first ground of rejection is of claims 1-3, 14 and 15 under 35 U.S.C. 103(a) as being unpatentable over the combined disclosures of Baker et al. (USPN 5,362,496), Yamaguchi et al. (USPN 5,820,877) and Majeti (USPN 5,599,554). (The Examiner inadvertently presents the last three digits of Majeti as '544.)

The Examiner's characterization of the scope of the herein rejected claims is inaccurate, assuming that the first sentence of that characterization (Examiner's Answer, p. 3) was intended to reflect the scope of the broadest of these claims, claim 1. Claim 1 recites neither an "adhesive patch" nor an "essential oil" nor that nicotine is a "drug" though it understood from the state of the art that the function of the transdermal therapeutic system (hereinafter "TTS") is to deliver nicotine to a user of the TTS to aid in the user's efforts to cease smoking.

"The compounds are well known for scent masking as well, specifically peppermint and carvone (col. 20, line 26-32)" (Examiner's Answer, p. 3) is a mischaracterization of the Baker et al. disclosure cited by the Examiner, which actually reads: "In addition, the *lozenge* may contain a *flavorant*, for example, a candy *taste*, such as chocolate, orange, vanilla, and the like; essential oils such as

peppermint, spearmint or the like; or other *flavors*, such as aniseed, eucalyptus, 1-menthol, carvone, anethole and the like, to mask the *taste* of nicotine.” Thus, the Examiner mischaracterizes the portion of Baker et al. cited by him as (1) relating to scent masking whereas it relates to flavoring and (2) as highlighting peppermint and carvone or distinguishing them from other recited substances whereas it does not do so.

As noted in the Appeal Brief, the Examiner’s analysis of Baker et al. conflates disparate Baker et al teachings relating only to transdermal administration and only to transmucosal administration. The Examiner’s Answer weaves the disparate disclosures together to create an impression that Baker et al. is particularly relevant, whereas it is not. For example, the Examiner states that the transmucosal “presentation” may be an ointment or lotion. (Examiner’s Answer, p. 3.) The Examiner leaves it to the reader to assume, incorrectly, that Baker et al. discloses ointments or lotions which are suitable for transdermal administration. Why, otherwise, would the Examiner have made the aforementioned statement? Baker et al does, in fact, disclose that the oral dosage form for delivery of nicotine through the oral mucosa may be an ointment or gel, for example. (Col. 16, line 10.) There is not the slightest suggestion that such ointment or gel would also be suitable for transdermal delivery of nicotine. Moreover, one would not incorporate

in a formulation for transdermal delivery of nicotine a substance disclosed as a flavorant.

In addition to being based on the aforementioned conflation of disparate disclosures of Baker et al, the Examiner's analysis contradicts itself. First, the conflation and mischaracterization: "The transdermal formulation includes nicotine as a drug and essential oils. The essential oils suggested are spearmint and peppermint oil, along with monoterpene ketones and alcohols such as 1-menthol and carvone (col. 6, lin. 6-59; col. 20, lin. 26-36). The reference states the formulation can be made into both transmucosal and transdermal formulations." (Examiner's Answer, paragraph bridging pages 3 and 4.) It is not understood why the Examiner cited col. 6, lines 6-59 of Baker et al. because there is no disclosure therein of the use of essential oils or monoterpene ketones and alcohols. Col. 20, lines 26-32 of Baker et al relates to flavorants for lozenges for transmucosal delivery of nicotine. It is revealing that the Examiner cites no particular portions of Baker et al. for the following sentences at pages 3 and 4, respectively, of the Examiner's Answer: (1) "The transdermal formulation includes nicotine as a drug and essential oils." (2) "The reference states the formulation can be made into both transmucosal and transdermal formulations." As to (1), Baker et al does not disclose any transdermal formulation including an essential oil. As to (2), if the

Examiner means that Baker et al. discloses that any one formulation can be used for either transmucosal or transdermal delivery of nicotine, that is not true.

Then, after conflating disparate disclosures of and mischaracterizing Baker et al. to conclude that Baker et al. discloses a formulation for delivery of nicotine transdermally, the Examiner contradicts himself by stating (Examiner's Answer, page 4): "Though the reference discloses transmucosal delivery of nicotine and carvone, it does not disclose the formulation in a patch presentation." It is assumed that the Examiner intends "patch presentation" to mean a transdermal delivery system. To the rejection as set forth in the Final Action, the Examiner has now added this contradiction.

The Examiner also mischaracterizes the arguments regarding Baker et al. in the Appeal Brief by asserting at page 9 of the Examiner's Answer: "Applicant takes a far too narrow interpretation of the art and does not take into consideration that the examples in the specification do not limit the scope of the invention once the concept is well known." This assertion is inappropriate, considering that appellant's arguments make no reference to any example in Baker et al. but, rather refer to the broad disclosures of Baker et al. Moreover, appellant is unable to reply to the Examiner's assertion of a "concept [which] is well known" because appellants cannot comprehend or even imagine to what supposedly well known concept the Examiner is alluding.

In discussing Majeti (Examiner's Answer, p. 9), the Examiner characterizes 1-menthol as "a compound recited by applicant as to be congruent to the scent/taste masking compounds of the instant claims." According to "Webster's New Collegiate Dictionary," 1977 edition, "congruent" can be a synonym of "congruous" and "congruous" can mean "being in agreement, harmony, or correspondence." What the Examiner is, therefore, stating is that applicant has stated that 1-menthol, which is a monoterpene alcohol, and monoterpene ketones are equivalent. On the contrary, however, the application demonstrates by experiments the superiority of monoterpene ketones for applicant's objective to neutralize the characteristic smell of nicotine or to mask it with a more pleasant smell and concludes the experiments show, *inter alia*, "a very surprisingly clear advantage of menthone over menthol" (page 6, lines 1-2), "spearmint oil, which is dominated by carvone and is practically free from menthol, yielded the best results" (page 6, lines 8-9), and "Overall, this demonstrates a clear advantage of monoterpene ketones, or mixtures of monoterpene alcohols and monoterpene ketones, over pure monoterpene alcohols." (The undersigned wishes to take this opportunity to correct the record. The statement in the Remarks, page 3, of the Amendment After Final Rejection dated April 3, 2003 that "menthol or other monoterpene alcohols are now excluded from the scope of the claims" is

inaccurate. The claims require the presence of a monoterpene ketone without excluding the presence, in addition, of a monoterpene alcohol.)

The Examiner asserts Majeti establishes “the art recognized nexus between transdermal and transmucosal formulations: (Examiner’s Answer, p. 4.) The prior art does not suggest, however, that all or even most or many formulations suitable for transmucosal delivery of nicotine or other “drug” are also suitable for transdermal delivery. Moreover, one would not incorporate in a transdermal formulation substances disclosed by Baker et al. only as flavorants because the sense of taste is not involved in transdermal treatment nor does Baker et al. teach or make obvious that monoterpene ketones are superior to monoterpene alcohols in masking nicotine odor. It is interesting also to note that Example II of Majeti, a transmucosal delivery system, includes flavoring whereas Example I, a transdermal delivery system, does not

Appellant does not disagree with the Examiner’s statements that Yamaguchi teaches that menthol and mentha, which are monoterpene alcohols, may be used as absorption enhancers but does not mention monoterpene ketones. (Examiner’s Answer, page 4.) Appellant does, however, disagree with the Examiner’s statement that “Applicant has ignored the combination of the transmucosal formulation of ‘496 into the delivery device of ‘877, under the knowledge evidenced by [‘554].” (Examiner’s Answer, page 10.)

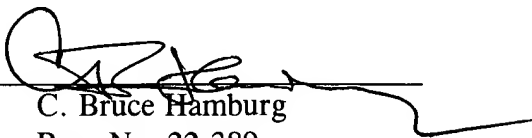
The rejection assumes it would have been obvious to one of ordinary skill in the art to incorporate into a TTS, monoterpene which the prior art (Baker et al.) discloses only as flavoring whereas incorporation of a flavoring in a TTS would be nonsensical as confirmed by comparison of Examples I and II of Majeti. Hence, no case of prima facie obviousness has been made. The prior art (Yamaguchi et al.) does teach the use of 1-menthol or mentha oils, which are monoterpene alcohols, as absorbefacients. The present application shows, however, monoterpene alcohols to be significantly inferior to monoterpene ketones for the masking of nicotine odor, which is an unanticipated, surprising result and which would rebut prima facie obviousness. From this it is also apparent that the cited prior art also does not make obvious the recited proportions or the specific compounds recited in dependent claims.

Appellant's foregoing arguments are equally applicable to the rejection of claims 6, 8 and 16, which are claims directed to a process for masking the odor of nicotine which are parallel to TTS claims 1, 2 and 15, respectively. In this rejection, to the combination of Baker et al., Yamaguchi et al. and Majeti the Examiner has added Briskin et al. (USPN 3,559,655) and DeFoney et al. (USPN 4,039,653). Neither Briskin et al. nor DeFoney et al. teach or make

obvious appellant's discovery that monoterpene ketones are substantially superior to monoterpene alcohols for masking nicotine odor in a TTS.

Respectfully submitted,

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